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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,166	09/10/2001	Tadashi Kokubo	06082.0026	9560

7590 11/26/2003

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,166

Applicant(s)

KOKUBO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on August 11, 2003 has been entered. Claims 1-8, 10-13 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 4-5, 7-8, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547.

Gray discloses particulate material comprising ceramic microspheres having a diameter in the range of 5 to 200 microns wherein the microsphere is made of 99.99% pure yttria (Y₂O₃) (see claim 1, and col 7, lines 1-66). Gray discloses methods of preparing such particulates by preparing a microsphere and then subjects the microspheres to neutron beams to product beta-radiation emitting radionuclide of yttrium-90 (col 7, lines 35-37). Gray also teaches that the process of melting is done by employing a thermal/plasma process of spray drying. (col 5, line 34-45; col 6, lines 25-40). Gray fails to specifically state that his microspheres are in the shape of a sphere.

Modifying the shapes of microspheres are viewed to be a design choice and absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the shape of Gray's microspheres to enhance its clinical efficacy.

Claims 1-8, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547 in view of Day US Patent 5,302,369 and Huang US Patent 5,073,404.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant appears to be arguing that there is no motivation to make Gray's microspheres spherical because there is no suggestion in Day that "void-free" microspheres are superior to the hollow or cup shaped microspheres of Gray. (see Response at 8).

In response Examiner first states that Day and Gray both teach microspheres containing yttrium oxide (yttria), thus, their teachings are within the same field of endeavor. Second, Day further provides in the art that even spherical microspheres are expected to provide suitable radiation therapy. Finally, Applicant's assertion that Gray's microspheres do not contain at least 99% by weight of an oxide of yttrium, is not correct, because Gray specifically states microspheres are from 99.99% pure yttria. (see col 7, lines 5-10). Yttria is an oxide form of Yttrium. (see attached RN 1314-36-9). Therefore, all elements of the instant claims are taught by the combined teachings of the references.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Gray teaches microspheres that contain at least 99.99% yttrium oxide. Gray also teaches the use of other ingredients such as silica in his

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microspheres (col 4, lines 16-26). Day provides adequate expectation of success when microspheres are in the spherical form. Day also teaches that Yttrium can be incorporated into the microspheres in combination with phosphorus (see col 6, lines 40-62). Day indicates that radioactive microspheres can contain silica and/or further be coated. Thus, the combined teachings of the references render the instant claims obvious for the reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123



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